

Louis H. Weinstein (LW 7868)

Andrew J. Miller (AM 8160)

BUDD LARNER, P.C.

150 John F. Kennedy Parkway

Short Hills, New Jersey 07078

(973)379-4800

Attorneys for Defendants and

Counterclaim Plaintiffs

Dr. Reddy's Laboratories, Ltd. and

Dr. Reddy's Laboratories, Inc.

UNITED STATES DISTRICT COURT

ASTRAZENECA AB, AKTIEBOLAGET

HÄSSLE and ASTRAZENECA LP, KBI

INC. and KBI-E, INC.,

Plaintiffs and

Counterclaim Defendants,

v.

DR. REDDY'S LABORATORIES, LTD. and

DR. REDDY'S LABORATORIES, INC.

Defendants and

Counterclaim Plaintiffs.

DRL DEFENDANTS' OPPOSITION

TO ASTRAZENECA'S MOTION TO STRIKE

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Submitted With DRL's Opposition To Astra's Motion To Strike

- Fourth Declaration of Harry G. Brittain, Ph.D., FRSC
- Exhibits to the Fourth Brittain Declaration
 - A. Summary of credentials and experience and curriculum vitae of Harry G. Brittain, Ph.D., FRSC

I. Preliminary Statement

The Rules of this Court give DRL the right of reply on its Motion for Summary Judgment, which absent extraordinary circumstances should be the last word. Not satisfied with this procedure, Astra moved to strike DRL's Summary Judgment Reply ("DRL Reply") and all of DRL's Reply Declarations. However, each of DRL's Reply papers fairly met the arguments and objections raised in Astra's Opposition, and there is no basis to strike any of them.

The evidentiary points Astra raises are insubstantial. Moreover, there can be no prejudice to Astra because they had all the documentary evidence submitted in DRL's Reply, and they did not complain that it was inaccurate. Specifically, they did not argue that the ANDA and DMF documents submitted with the Reply Declarations are not accurate, or that the interrogatory response that initially summarized them was not accurate. Instead, they seek to strike DRL's Reply because they do not like the substance.

Astra's motion to strike prejudicially delays consideration of DRL's Summary Judgment Motion and is improperly used to respond to DRL's Reply. Because DRL's Reply and the supporting Declarations are all in the nature of a measured and proper response to Astra's Opposition, and do not raise new arguments, Astra's Motion to Strike and Astra's alternative request for a surreply should be denied.

II. DRL's Reply Papers Properly Responded To Matters Raised In Astra's Opposition

DRL's Reply papers -- the Reply Memorandum and the Reply Declarations of Dr. Brittain, Dr. Sekar, and Mr. Weinstein -- all responded to points raised by Astra in its Opposition to DRL's Motion for Summary Judgment. The declarations noted inadequacies in Astra's opposition papers and they responded to Astra's criticism of the declaration that Dr. Brittain submitted in support of DRL's motion. DRL's Reply papers did not raise new arguments that

would warrant any surreply, nor did they introduce new facts that could create any *bona fide* factual issues. The Court should deny Astra's motion in its entirety.

A. Dr. Brittain's 3rd Declaration Was Fair And Proper Reply

The Brittain Declaration submitted with DRL's Reply (the 3rd Brittain Declaration) did no more than respond to the Luk Declaration and criticisms raised in Astra's Opposition brief. Responding to Dr. Luk's Declaration, Dr. Brittain pointed out the deficiencies in Dr. Luk's opinions concerning DRL's processes and product. Dr. Brittain also addressed Astra's criticism that he had not based his opinions in support of DRL's Motion for Summary Judgment on review of the actual ANDA and DMF at issue. Specifically, Dr. Brittain reiterated his conclusions of noninfringement based on review of the relevant ANDA and DMF documents. He did not offer new grounds of noninfringement. Accordingly, his declaration was fair reply, and does not call for surreply.

1. Dr. Brittain's 3rd Declaration Was A Direct Response To The Luk Declaration

Dr. Brittain's 3rd Declaration properly responded to the opinions in Dr. Luk's Declaration. Dr. Brittain pointed out inadequacies in Dr. Luk's Declaration and Astra's opposition; this is not grounds to strike and it does not justify a surreply.

For example, as initially discussed at pp. 9-10 of DRL's Memorandum in Support of DRL's Motion for Summary Judgment ("DRL's Memo"), Astra obtained claims 11 and 20 of the '424 patent by arguing during prosecution that these claims were distinguishable from the prior art precisely because they were limited to processes that used water to recover omeprazole magnesium from solution. *See* DRL Ex. 8 p. 5. Accordingly, to prove infringement of these claims, Astra must establish that DRL's process does in fact use water to recover omeprazole magnesium from solution. At ¶ 4 of his Declaration, Dr. Luk speculated that there is a

“possibility” that DRL infringes the ‘424 patent. Against this backdrop, it was entirely appropriate for Dr. Brittain to point out that “nowhere in his Declaration does Dr. Luk discuss how the DRL process uses water to recover omeprazole magnesium from solution.” 3rd Brittain Decl. ¶ 7. The fact that Dr. Brittain pointed to a glaring hole in Astra’s case is not a legitimate reason to strike his 3rd Declaration.

At page 12 of its Memo, DRL pointed out that Astra could not prove infringement of claim 10 of the ‘960 patent because Astra has no evidence that DRL forms a core with the necessary crystallinity. On its face, claim 10 of the ‘960 patent is a process claim that includes the limitation of “forming a core material containing omeprazole magnesium salt, said salt having at least 70% crystallinity as determined by x-ray powder diffraction.” DRL Ex. 3, claim 10, step (a). Thus, to prove infringement of this claim, Astra must show that DRL’s process for making its finished drug product includes the step of forming the specified core material. Dr. Luk speculated that the record “suggests” that DRL’s product “very possibly contains highly crystalline omeprazole magnesium as required by the claims of the patents-in-suit.” Luk Decl. ¶ 6. Against this backdrop, Dr. Brittain directly and properly responded to Dr. Luk by pointing out that “[n]owhere in his declaration does Dr. Luk opine why it would be expected that the DRL process for manufacturing its finished drug product would entail the formation of a core material containing omeprazole magnesium that is at least 70% crystalline by x-ray powder diffraction.” 3rd Brittain Decl. ¶ 10.

DRL’s Memo also discussed the 70% crystallinity limitation of Astra’s product claims. *See, e.g.*, DRL Memo pp. 7, 11 and 13. Astra’s product claims, *i.e.*, claim 1 of the ‘424 patent and claims 1 and 22 of the ‘960 patent, all require omeprazole magnesium that is at least 70% crystalline as determined by x-ray powder diffraction. Unable to find infringing crystals in DRL’s finished product using the test method specified in the claims, Dr. Luk speculated,

without discussing the details of DRL's process for manufacturing its finished drug product, that "it would make sense for DRL's product to contain highly crystalline omeprazole magnesium." Luk Decl. ¶ 5. In a direct and proper response, Dr. Brittain discussed why DRL would not be expected to have problems using amorphous material in the process that DRL uses to make its finished drug product and Dr. Brittain properly observed that Dr. Luk "does not indicate how the use of amorphous drug substance would present problems in DRL's manufacture of its finished drug product." 3rd Brittain Decl. ¶ 12.

All of this was proper reply, demonstrating that Dr. Luk's speculation could not create a disputed issue of material fact. Under this Court's Rules, to avoid giving an unfair advantage to the party opposing summary judgment, the moving party is allowed to file reply papers that properly address new material issues raised in the opposition papers. *Bonnie & Co. Fashions, Inc. v. Bankers Trust Co.*, 945 F. Supp. 693, 708 (S.D.N.Y. 1996). Clearly, Dr. Brittain could not know what Dr. Luk would or would not say in his Declaration until Astra submitted it with its Opposition. Thus, the opinions in Dr. Brittain's 3rd Declaration concerning the deficiencies in Dr. Luk's Declaration are all in the nature of a proper reply on summary judgment. *See id.* That Dr. Brittain was able to succinctly point out the dispositive inadequacies in Dr. Luk's Declaration is not a basis for granting Astra's Motion to Strike.

2. Dr. Brittain's 3rd Declaration Was Not A Belated Attempt To Defeat An Evidentiary Problem

In addition to its position that this Court should not even hear Dr. Brittain's response to Dr. Luk's Declaration, Astra argues in its Motion to Strike that the 3rd Brittain Declaration should be stricken as "a belated attempt to defeat an evidentiary problem." Astra Motion p. 4. Thus, Astra asserts that the 2nd Brittain Declaration was inadmissible and that the 3rd Brittain Declaration was improperly late. Astra is wrong on both counts. First, because the 2nd Brittain

Declaration was in fact admissible there was no evidentiary problem. Second, even if Astra's Opposition did raise a proper evidentiary objection to Dr. Brittain's 2nd Declaration -- and DRL maintains that there was no problem -- it was appropriate and timely for DRL to submit the 3rd Brittain Declaration with DRL's Reply as a response to the alleged deficiency.¹

a. Dr. Brittain's 2nd Declaration Was In Fact Admissible Under Either Federal Rule Of Evidence 703 or 1006

Dr. Brittain's 2nd Declaration was admissible under either Federal Rule of Evidence 703 or 1006 at the time it was submitted with DRL's Motion for Summary Judgment.

i. Rule 703 Allowed Dr. Brittain To Rely On The Detailed Facts Presented In DRL's Sworn Answer To Interrogatory No. 10

Dr. Brittain's 2nd Declaration was admissible under Federal Rule of Evidence 703. "Rule 703 expressly authorizes the admission of expert opinion that is based on 'facts or data' that themselves are inadmissible, as long as the evidence relied upon is 'of a type reasonably relied upon by experts in the particular field in forming opinions.'" *Monsanto Co. v. David*, 516 F.3d 1009, 1016 (Fed. Cir. 2008), *quoting* Fed. R. Evid. 703. Moreover, under Rule 703 "an expert may rely on data that she did not personally collect." *Gussack Realty Co. v. Xerox Corp.*, 224 F.3d 85, 94 (2d. Cir. 2000). "The Federal Rules of Evidence specifically provide that an expert may rely on facts or data 'perceived by *or* made known to the expert at or before the hearing.'" *Id.* at 94-95, *quoting* Fed. R. Evid. 703 (emphasis supplied by the Second Circuit). Dr. Brittain's 2nd Declaration was admissible under Federal Rule of Evidence 703 because he relied on the type of facts reasonably relied on by experts in his field.

¹ The 1st Brittain Declaration, which is not at issue here, was submitted in November of last year in support of DRL's Reply to Astra's Explanation of Infringement Discovery. The 2nd Brittain Declaration was submitted with DRL's Motion for Summary Judgment. The 3rd Brittain Declaration was submitted with DRL's Summary Judgment Reply.

Dr. Brittain has extensive experience in the manufacture and characterization of pharmaceutical drugs. 2nd Brittain Decl. ¶¶ 1-8. He has written and researched extensively on the subject of pharmaceutical physics and physical pharmacy. 2nd Brittain Decl. ¶ 5. He regularly lectures on these topics at university and pharmaceutical symposia. *Id.* His industrial work experience includes a position as the Director of Pharmaceutical and Chemical Development at Ohmeda Pharmaceutical Products Division, Inc. (Murray Hill, New Jersey), where he was responsible for all later-stage aspects of drug development and the management of analytical, pharmaceutical, and chemical development groups. *Id.* ¶ 2. He is a Fellow of the American Association of Pharmaceutical Sciences and a Fellow of the Royal Society of Chemistry. *Id.* ¶ 4. Astra did not dispute that Dr. Brittain was qualified to give the opinions stated in his Declarations.

In coming to the opinions presented in his 2nd Declaration, and as stated therein, Dr. Brittain relied, in part, on the detailed facts submitted to the Court in DRL's sworn Answer to Interrogatory No. 10. 2nd Brittain Decl. ¶¶ 36, 41. DRL's sworn Answer to that Interrogatory presented detailed facts about DRL's processes, including temperature, pressure, time, weight, reagents, equipment and processing steps. DRL Ex. 6, pp. 9-16. As stated in Dr. Brittain's 4th Declaration, submitted herewith, these detailed facts are the type of facts on which an expert in his field would reasonably rely in forming opinions as to whether a pharmaceutical process did or did not infringe patent claims directed to manufacturing methods. 4th Brittain Decl. ¶¶ 6, 8. Thus, Dr. Brittain's 2nd Declaration was admissible under Rule 703 even if DRL's sworn Answer to Interrogatory 10 was not. *Id.* Moreover, DRL's sworn Answer to Interrogatory No. 10 was itself admissible under Federal Rule of Evidence 1006 as a summary.

ii. Rule 1006 Allowed Dr. Brittain To Rely On The Detailed Summary In DRL's Sworn Answer To Interrogatory No. 10

Dr. Brittain was also allowed to rely on the detailed summary presented in DRL's sworn Answer to Interrogatory No. 10 under Federal Rule of Evidence 1006, which provides that the "contents of voluminous writings . . . which cannot conveniently be examined in court may be presented in the form of a chart, summary or calculation." Fed. R. Evid. 1006. Well before DRL moved for summary judgment, DRL produced the portions of its DMF and ANDA that describe the manufacture of its active ingredient and the manufacture of its finished drug product. DRL Exs. 19, 20; 3rd Weinstein Decl. ¶¶ 9-15; Sekar Decl. ¶¶ 6-7.

Astra argued in its Opposition to DRL's Summary Judgment Motion that DRL's Interrogatory Answers are unqualified expert opinion and conclusory hearsay. However, Astra had the portions of the DMF and ANDA that corroborate the detailed summary relied on by Dr. Brittain in his 2nd Declaration, and Astra did not argue in its Opposition that the detailed summary presented in DRL's sworn Answer to Interrogatory No. 10 was in any way inaccurate. *See* Astra Opposition pp. 14-15. Moreover, the DMF and ANDA documents produced to Astra are the documents that underlie this case. They were authenticated by Dr. Sekar and would be admissible. Sekar Decl. ¶¶ 6, 7. Thus, the summary presented in DRL's Answer to Interrogatory No. 10 was itself admissible under Rule 1006 and it was appropriate for Dr. Brittain to rely on it in his 2nd Declaration. *See F.D.I.C. v. Key Fin. Serv., Inc.*, No. 89-2366-DPW, 1999 WL 34866812, at *10 (D. Mass. Dec. 23, 1999) (spreadsheets were admissible under Rule 1006 because the underlying documents were made available to the other party and it appeared from the affidavits submitted by the proponent of the summaries that the underlying documents were independently admissible).

**b. DRL Properly Submitted The 3rd Brittain Declaration
In Response To The Objections Raised Against The 2nd
Brittain Declaration**

As discussed above, Dr. Brittain's 2nd Declaration offered in support of summary judgment was entirely appropriate. However, assuming that Astra's Opposition raised a valid evidentiary objection to Dr. Brittain's reliance in his 2nd Declaration on DRL's Answer to Interrogatory No. 10, it was entirely appropriate for DRL to address the objection in its Reply. It was equally appropriate for DRL to submit Dr. Brittain's 3rd Declaration to cure the alleged deficiency.

Specifically, Astra objected to Dr. Brittain's 2nd Declaration on the ground that he should have relied on the direct evidence of DRL's processes, *i.e.*, the relevant pages from DRL's DMF and ANDA. Astra Opposition p. 14. Foreseeing that DRL could easily correct the alleged problem, Astra conceded that "Dr. Brittain's Declaration is nothing more than hearsay at this point." *Id.* (emphasis added). As anticipated by Astra, DRL's Reply corrected the alleged deficiency with a proper and sufficient response.

In particular, in response to Astra's evidentiary objection, Dr. Brittain reviewed the pages from the DMF and ANDA that Astra said Dr. Brittain should have reviewed. 3rd Brittain Decl. ¶ 2. As stated in his 3rd Declaration, after reviewing the relevant portions of the DMF and ANDA, the opinions stated by Dr. Brittain in his 2nd Declaration concerning DRL's processes and products did not change. 3rd Brittain Decl. ¶¶ 4, 8. Thus, any evidentiary concern regarding the 2nd Brittain Declaration was addressed.

It is within the Court's discretion to let Dr. Brittain supplement his earlier declaration. *See* Fed. R. Civ. P. 56(e)(1) (court may permit an affidavit "to be supplemented" by "additional affidavits"). The opinion in *Barr v. Frannet, LLC*, No. 3:07-CV-1022-M, 2008 WL 59295 (N.D. Tex. Jan. 3, 2008), is instructive. In *Barr*, the plaintiff filed a motion to strike an affidavit on a

host of grounds, including that the original affidavit lacked language about the information being true and correct under penalty of perjury, that the affidavit was conclusory and speculative, that the affiant failed to explain how he had personal knowledge and that the affiant did not attach the business records upon which he relied. To cure the alleged defects the defendant submitted two supplemental affidavits from the affiant. The *Barr* court denied the motion to strike, holding that the affidavit and the supplemental affidavits should not be stricken because any alleged defects had been cured. *Id.* at *2. This Court should reach the same conclusion here. Any alleged defects in the 2nd Brittain Declaration, to the extent they existed at all, have been properly cured and the motion to strike Dr. Brittain's 3rd Declaration should be denied.

Astra cites *Playboy Enters. v. Dumas*, 960 F. Supp. 710, 720 n.7 (S.D.N.Y. 1997), and *Sigmon v. Parker Chapin Flattau & Kimple*, 901 F. Supp. 667, 677 n.5 (S.D.N.Y. 1995), as authority for why Dr. Brittain's 3rd Declaration should be stricken. Astra Motion p. 2. These cases, however, simply do not address the use of supplemental affidavits in a response to an evidentiary objection. Rather, these cases stand only for the proposition that courts need not consider entirely new substantive arguments made for the first time in a reply brief. *Playboy*, 960 F. Supp. at 720 n.7 (refusing to consider complex and possibly dispositive argument raised for first time in reply brief where the opening memorandum did not even hint that this argument might be made); *Sigmon*, 901 F. Supp. at 677 n.5 (refusing to consider former employer's argument that discrimination plaintiff had not met the second element of a *prima facie* case when the argument was raised for the first time in a reply brief).

In the instant case, Dr. Brittain's 3rd Declaration does not raise any new substantive argument for the first time. First, the evidentiary recitations in Dr. Brittain's 3rd Declaration do not raise substantive arguments. Rather, they directly address an evidentiary objection raised in Astra's Opposition. Second, the opinions in Dr. Brittain's 3rd Declaration are not "new." To the

contrary, Dr. Brittain states that he reviewed the material that Astra maintains he should have reviewed in the first instance and that his opinions remained the same. 3rd Brittain Decl. ¶¶ 4, 8. Accordingly, Astra's cases provide no support at all for striking Dr. Brittain's 3rd Declaration.

B. The Sekar Declaration Properly Responded To The Evidentiary Objection In Astra's Opposition

Dr. Sekar's Declaration did no more than authenticate the portions of the ANDA and DMF that are the basis for this case, documents which had been previously produced to Astra. Moreover, is proper for a District Court to consider affidavits and exhibits submitted with a summary judgment reply, even if they address issues not raised in the moving papers, where they directly respond to issues raised in the opposition. *Mattera v. Clear Channel Commc'n, Inc.*, 239 F.R.D. 70, 74 n.4 (S.D.N.Y. 2006); *see Cifarelli v. Village of Babylon*, 93 F.3d 47, 53 (2d Cir. 1996) (considering evidence submitted on reply where the record shows that the plaintiff "was fully aware prior to the defendants' reply" of the issue to which the evidence pertained). In replying to Astra's evidentiary criticisms, Dr. Brittain reviewed the ANDA and DMF documents that Astra said he should have used as the basis for his opinions. Simply to avoid an authenticity objection, DRL submitted the Sekar Declaration to authenticate these very documents. Sekar Decl. ¶¶ 6, 7. Dr. Sekar's Declaration (¶¶ 1-5) is plainly sufficient to establish Dr. Sekar as a DRL employee capable of authenticating DRL's DMF and ANDA documents on personal knowledge. *See Koon Chun Hing Kee Soy & Sauce Factory, Ltd. v. Star Mark Mgmt., Inc.*, No. 04-CV-2293 (JFB)(SMG), 2007 WL 74304, at *2 (E.D.N.Y. Jan. 8, 2007) (corporate officer may offer evidence in declaration based on personal knowledge obtained in review of company records).

Astra's argument that it needs a deposition of Dr. Sekar is a red herring. Astra did not argue that Dr. Sekar is incompetent to authenticate the documents, Astra did not allege that the

documents authenticated by Dr. Sekar are not authentic, and Astra did not ask for the deposition of a custodian of records who could authenticate documents when it asked for portions of DRL's DMF and ANDA in Astra's Explanation of Infringement Discovery, or at any other time prior to Astra's Motion to Strike. Astra's attempt to delay DRL's Motion for Summary Judgment by requesting the unnecessary deposition of Dr. Sekar should be rejected.

C. The 3rd Weinstein Declaration Is A Proper Response To Astra's Opposition Papers

Astra's argument that the 3rd Weinstein Declaration should be stricken is misplaced because the 3rd Weinstein Declaration responds directly and appropriately to matters raised in Astra's Opposition. Paragraphs 1-3 of the 3rd Weinstein Declaration are preliminary in nature. Paragraphs 4-13 respond to Astra's insinuation in its Opposition papers that DRL did not properly or promptly produce the documents required by the Court's May 5, 2008 Ruling. Paragraphs 14 and 15 merely attach copies of the portions of the DMF and ANDA produced to Astra in compliance with the Court's Rulings and authenticated by Dr. Sekar.² The remaining paragraphs, Paragraphs 16-20, attach and authenticate portions of the Patent Office prosecution history of one of Astra's patents in suit, which provide background for DRL's reply to Astra's argument that Astra is entitled to rely on the doctrine of equivalents. *See* Astra Opposition p. 24. Thus, the entire 3rd Weinstein Declaration is no more than a proper response to Astra's Opposition. There is no basis to strike it.

III. Astra Has Not Identified Any New Arguments That Would Justify The Filing Of A Surreply

Astra's alternative request for leave to file a surreply should also be denied. Astra did not identify a single new argument in DRL's Reply that would warrant a surreply. Moreover, they

² DRL notes that ¶ 15 of the 3rd Weinstein Declaration contains a typographical error. That Paragraph should have referred to "¶ 7" of the Sekar Declaration, and not to "¶ 6."

are not prejudiced by the documents from the ANDA and DMF or any of the other substantive documentary evidence in the declarations, all of which they previously had. Moreover, DRL's Reply and all of the supporting materials properly addressed the arguments and objections raised in Astra's Opposition and demonstrate that there is no disputed material issue of fact. Astra has not been unfairly prejudiced by anything in DRL's Reply papers and there is no basis for allowing Astra to file a surreply. *See Travelers Ins. Co. v. Buffalo Reinsurance Co.*, 735 F. Supp. 492, 495 (S.D.N.Y.) (denying leave to file surreply), *vacated in part on other grounds*, 739 F. Supp. 209 (S.D.N.Y. 1990). Astra simply wants to have the last word on DRL's motion -- a last word that the Rules do not allow.

IV. Conclusion

For the foregoing reasons, Astra's Motion to Strike should be denied and Astra should not be given leave to file a surreply.

Dated: September 4, 2008

Respectfully submitted,

s/ Louis H. Weinstein
 Louis H. Weinstein (LW 7868)
 Andrew J. Miller (AM 8160)
 BUDD LARNER, P.C.
 150 John F. Kennedy Parkway
 Short Hills, NJ 07078
 (973) 379-4538 (tel)
 (973) 379-7734 (fax)
 E-mail: lweinstein@budd-larner.com

*Attorneys for Defendants
 Dr. Reddy's Laboratories, Ltd. and
 Dr. Reddy's Laboratories, Inc.*

CERTIFICATE OF SERVICE

I certify that on this 4th day of September, 2008, I caused a true and correct copy of DRL DEFENDANTS' OPPOSITION TO ASTRAZENECA'S MOTION TO STRIKE be served upon counsel for AstraZeneca in the following manner:

By ECF, E-MAIL AND FEDERAL EXPRESS

Errol B. Taylor, Esq.
Milbank, Tweed, Hadley &
McCloy LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
Facsimile: 212-530-5219


